



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Press Office

## Press release

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# New EMA guidance on development of antibacterials to help in the fight against multidrug-resistant pathogens

The European Medicines Agency (EMA) today released an addendum to the guideline on the evaluation of medicinal products indicated for the treatment of bacterial infections. One of the most important aspects of the addendum is that it outlines a new approach facilitating the development of antibacterial agents targeted against multidrug-resistant (MDR) pathogens where patients have very limited or no remaining treatment options. It also gives guidance on data-gathering strategies to support the benefit-risk evaluation as part of the marketing-authorisation process for different indications.

This addendum complements the guideline on evaluation of medicinal products indicated for treatment of bacterial infections.

"Infections by multidrug-resistant bacteria in the European Union are a major public health burden causing 25,000 extra deaths per year," said Guido Rasi, Executive Director of the EMA. "We urgently need new antibacterials to tackle the growing challenge of antimicrobial resistance. One of our key activities in helping to bring these medicines to the market is to provide clear guidance for companies developing these medicines. With this addendum we are defining a new approach to facilitate the development of new antibacterials targeting multidrug resistance in areas where there are no or only limited therapeutic options. It marks an evolution in the way we think about bringing new antibiotics to patients."

The addendum provides recommendations on:

- clinical development for medicines intended to treat five major infection types - community-acquired pneumonia, hospital- and ventilator-acquired pneumonia, urinary tract infections, intra-abdominal infections, skin and soft tissue infections, for which non-inferiority pivotal studies are acceptable;
- clinical development for medicines intended to treat acute otitis media, acute bacterial sinusitis, acute bacterial exacerbations of chronic bronchitis, inhalational antibacterial regimens in non-cystic fibrosis patients and for superficial skin infections, for which superiority studies could be required;
- clinical development of medicines for which limited clinical data may be accepted because they address unmet clinical needs such as the potential to treat infections due to MDR organisms for which only few or no remaining therapeutic options are available;



- clinical development of medicines for indications which could present problematic aspects, e.g. bacteraemia.

The publication of the addendum also includes more detailed guidance on issues such as patient-selection criteria and primary endpoints, including efficacy variables and the timing of assessment outcomes. This responds to requests from the pharmaceutical industry and academia during the public consultation on the guideline on the evaluation of medicinal products indicated for the treatment of bacterial infections, and at a workshop held at the EMA in 2011.

The addendum was released for consultation between July 2012 and January 2013. As part of the consultation process, the Agency invited experts in the field to discuss relevant aspects on the development of new antibacterials. Comments received during the consultation period, and at a further workshop in 2012, together with experience gained with novel agents, have guided the refinement of the new addendum.

### **Upcoming workshop on antibiotics development**

As part of its intensified effort to improve development strategies for antibiotics, the EMA is hosting a workshop on Friday, 8 November 2013, entitled '[Best use of medicines legislation to bring new antibiotics to patients and combat the resistance problem](#)'. The workshop will discuss regulatory options for approval of new antibacterials for human use and actions to increase appropriate use of antibiotics.

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### **Notes**

1. This press release, together with all related documents, is available on the Agency's website.
2. Addendum to the note for guidance on evaluation of medicinal products indicated for treatment of bacterial infections:  
[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2013/11/WC500153953.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2013/11/WC500153953.pdf)
3. This addendum complements the guideline on evaluation of medicinal products indicated for treatment of bacterial infections:  
[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2009/09/WC500003417.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500003417.pdf)
4. A non-inferiority trial has the primary objective of showing that the response to the investigational product is not clinically inferior to a comparative agent (active or placebo control). A superiority trial has the primary objective of showing that the response to the investigational product is superior to a comparative agent (active or placebo control).  
  
For more information, please refer to ICH Topic E 9 Statistical Principles for Clinical Trials:  
[http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Scientific\\_guideline/2009/09/WC500002928.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002928.pdf)
5. More on the 8 November workshop:  
[http://www.ema.europa.eu/ema/index.jsp?curl=pages/news\\_and\\_events/events/2013/09/event\\_detail\\_000781.jsp&mid=WC0b01ac058004d5c3](http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2013/09/event_detail_000781.jsp&mid=WC0b01ac058004d5c3)
6. More on antimicrobial resistance:  
[http://www.ema.europa.eu/ema/index.jsp?curl=pages/special\\_topics/general/general\\_content\\_000439.jsp&mid=WC0b01ac058002d4e9](http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000439.jsp&mid=WC0b01ac058002d4e9)

7. European Antibiotic Awareness Day is marked each year on 18 November. More information is available from the European Centre for Disease Prevention and Control website:  
[www.ecdc.europa.eu](http://www.ecdc.europa.eu)
8. More information on the work of the European Medicines Agency can be found on its website:  
[www.ema.europa.eu](http://www.ema.europa.eu)

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